

Meeting Report of the Special Committee for the Safety of Protein Hydrolysates in Cosmetics

7th Meeting

Date and Time: 12:30-13:10, December 1, 2012

Venue: Osaka International Convention Center (Room No. 1102)

Attendee: 14 committee members, 5 observers

Kayoko Matsunaga (Chair), Michiko Aihara, Yasuharu Itagaki, Atsuo Urisu, Zenichiro Kato, Reiko Kishikawa, Mitsuru Sawa, Shinichi Sugiura, Hiroyuki Tanaka, Yuko Chinuki, Reiko Teshima, Yuma Fukutomi, Akiko Yagami, Kazuo Akiyama (President of the Japanese Society of Allergology)

Absentee: Yoshiro Ikezawa, Michihiro Hide, Atsuki Fukushima, Eishin Morita (Committee member)
Kazumi Sasaki (National Institute of Technology and Evaluation)

Witness: Norio Takeda from Yuuka Co., Ltd.

Observer: Katsuhiko Takano, Hitoshi Sasa, Mariko Sugiyama (Japan Cosmetic Industry Association)
Masashi Nakamura (Fujita Health University)

Announcement:

Dr. Akiyama announced that the Society's board of directors had authorized, at the November 28 board meeting, another 2-year extension of the term of the Special Committee, which was initially 2 years, as there are still many matters to be considered. Continued assistance of the Committee members was requested. The present members will stay in the Committee until the board of representatives to be held in the spring of 2015.

Minutes:

1. Data collected through the "Cha no Shizuku"-induced case registration site as of November 26 – report by Dr. Matsunaga

Cases diagnosed as positive as of November 20: 1617

Females account for 1549 cases (95.8%) and males 68 (4.2%). The age of victims, mainly women in their 20s to 60s, ranges from 1 to 93 year old (45.6 in average). Fukuoka Pref. ranks first in the number of positive cases registered (222), followed by Hiroshima (105), Tokyo (102) and Aichi (98). Osaka, Hokkaido, Chiba, Saitama and other prefectures have rather low registration for the number of soap bars sold. There may be cases not having registered yet. It is estimated there are about 2,000 victims in these areas.

2. Glupearl 19S - property as antigen causing sensitization and cross-reactivity

It was confirmed to keep given rules as to indication of product and company names in making presentation, at the society conference, about the study performed using hydrolyzed wheat (other than Glupearl 19S) provided through the Committee.

Report by Dr. Tanaka:

(1) Effect of oral antigen challenge on mice sensitized through oral ingestion of hydrolyzed wheat

- (2) Effect of oral antigen challenge on mice having epicutaneously sensitized to hydrolyzed wheat
- (3) Future experiment plan

Mice sensitized to hydrolyzed wheat, when reared with feed containing no wheat components, rarely dies if aspirin and gluten are orally given. It is estimated that orally given gluten and wheat components are the key for the expression of symptoms. It is scheduled to make Glupearl 19S challenge test giving feed from which wheat components are removed.

Report by Dr. Kato:

Dr. Kato, considering treatment methods based on gene analysis and HLA steric structure, is seeking the possibility of joint research with genome researchers at RIKEN.

3. Number of cases reported by Yuuka Co., Ltd.

Data of the Pharmaceutical and Medical Devices Agency as of November 30, 2012 (data collected from May 20, 2011 through November 16, 2012)

- Medical certificates submitted by customers: 2721 (1285 cases were diagnosed as positive based on the diagnostic criteria)

*1500 cases were rejected due to no descriptions of wheat allergy or mere reference to food allergy.

- Notification from healthcare professionals to the Agency: 238 (43 cases were diagnosed as positive based on the diagnostic criteria)

Dr. Fukotomi asked about safety of ingredients other than Glupearl 19S contained in soap products released by Yuuka, and Yuuka orally explained the present condition.

4. Prognosis of, treatment for and measures against “Cha no Shizuku”-induced disorders

Enough number of cases has not been registered and further report is required.

5. Problems in relation to other cosmetics containing hydrolyzed proteins

Subsidy has been granted from the Ministry of Health, Labour and Welfare for the purpose of epidemiological study of the harm of hydrolyzed proteins other than Glupearl 19S as well as the safety of proteins contained in cosmetics. Dr. Matsunaga, Dr. Yagami and Dr. Sugiura are considering how to allocate it. The research, to be completed by March based on the subsidy, will be conducted making a good use of medical institution registration network. Each Committee member's assist is also requested.

The Committee will ask the Japan Cosmetic Industry Association for cooperation to make a list of food-based ingredients of cosmetics and to collect case data for focused items. It is expected that research can be continued after the expiration of this subsidy-based program once the system for such research is established.

6. Existence and challenge of the Committee after renewal

- Patients' clinical course has not been fully followed up. Exceptional cases where antibody level does not go down, antigen structure and sensitization mechanism need be further analyzed during

the renewed term. Proteins other than Glupearl 19S will be studied to attain a certain achievement.

- Necessary measures will be taken in response to the Dr. Fukutomi's proposal that the wheat allergy information collected by the Rheumatism & Allergy Information Center and the Committee should be integrated.

It was agreed that extracted Glupearl 19S should be requested on-line via a given form under the administration of Dr. Fukutomi (during the effective term of the Committee).

- Arrangements will be made based on the opinion by Dr. Morita that it will be useful to translate and release the context of the problem to the public.

Next meeting will be held at the occasion of the 25th spring meeting of the Japanese Society of Allergology (May, 2013)